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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,820	02/12/2004	Douglas A. Collins	07959.105024 (COP 1001 CO	5690
7590 07/06/2005 Madeline I. Johnston, Esq. KING & SPALDING LLP 45th Floor 191 Peachtree Street, N.E. Atlanta, GA 30303			EXAMINER LUKTON, DAVID	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,820

Applicant(s)

COLLINS ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

A restriction is imposed, as set forth below. First, however, the following subgenera are defined.

- G1:** The claimed compound does not contain any boron;
- G2:** The "molecule comprising B-10" is a peptide or amino acid;
- G3:** The "molecule comprising B-10" is a carbohydrate or nucleoside or carborane;
- G4:** The "molecule comprising B-10" can be whatever the claims permit, provided that G2 and G3 are excluded.



Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-10, 13-37, 40-44, 49, 54-68, 72, drawn to compounds of G2, provided that G1 is excluded.
2. Claims 1-44, 49, 54-68, 72 drawn to compounds of G3, provided that G1 is excluded.
3. Claims 1-9, 13-36, 40-44, 49, 54-68, 72, drawn to compounds of G4, provided that G1 is excluded.
4. Claims 24-43, 54-68, 72, drawn to compounds which do not contain B-10.
5. Claims 69-71, drawn to a method of using the compounds of Group 1.
6. Claims 69-71, drawn to a method of using the compounds of Group 2.

7. Claims 69-71, drawn to a method of using the compounds of Group 3.
8. Claims 69-71, drawn to a method of using the compounds of Group 4.

Claims 45-48, 50-53 are not grouped. These claims are not properly dependent. For example, claim 46 makes reference to "the non-metallic radionuclide of claim 3". However, there is no non-metallic radionuclide mentioned in any of claims 1, 2 or 3. In the event that applicants amend claims 46-48, 50-53 so that their dependence is proper, these claims will be grouped appropriately. Claims 73 and 74 are also not grouped; these are drawn to a "use", which is not a proper statutory class. These will also be grouped appropriately if amended in conformance with U.S. practice.

The claimed inventions are distinct.

Subgenus G1 has been created because it is somewhat unclear as to whether boron is required in all of the claims. It appears that claims 24-43, 54-68, 72 permit, but do not require boron. If, on the other hand, all of the claims do require boron, then applicants can just disregard group 4.

Groups 1 and 2 are distinguished on basis of the "molecule comprising B-10". However, in the event that either of Groups 1 or 2 is elected, and claims found allowable, the possibility of rejoining the other (of Groups 1 and 2) is not precluded. Group 4 might also be joined with Group 1 or 2.

Inventions {1-4} and {5-8} are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). However, in the event that one of Group 1-4 is elected, and the claims found allowable, the corresponding method claims will be rejoined for further examination (subject to the same limitations on structure of the compounds).

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound, with all substituent variables fully accounted for. In the event that one of Groups 5-8 is chosen for initial examination, election of one of the following is also required: (a) a method of treating a tumor-bearing mammal, or (b) a method of imaging a tumor.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments

submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800